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Private Limited,*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NEXGEN LIFESCIENCES, LLC,

Plaintiff,

v.

C.A. No. 2:22-cv-02901-MCA-JRA

MSN LABORATORIES PRIVATE LIMITED,

Defendant.

DEFENDANT MSN LABOROTIES PRIVATE LIMITED'S ANSWER

Defendant MSN Laboratories Private Limited (“MSN”), by its undersigned attorneys, answers the allegations in the Complaint filed by Plaintiff Nexgen Lifesciences, LLC (“Nexgen”) on May 18, 2022 in C.A. No. 2:22-cv-02901 as follows.

ANSWER TO COMPLAINT AND GENERAL DENIAL

For ease of reference, MSN incorporates the outline headings used in the Complaint. To

the extent that such headings make factual allegations, characterizations of fact, or legal conclusions, MSN does not adopt or admit such statements and instead denies them. Pursuant to Fed. R. Civ. P. 8(b)(3), MSN denies all allegations in Plaintiff's Complaint except those expressly admitted below.

SUMMARY OF THE ACTION

1. Defendant MSN Laboratories Private Limited ("MSN") is an Indian company that manufactures generic medications. Plaintiff Nexgen Lifesciences, LLC ("Nexgen") entered into an agreement with MSN for the distribution of certain generic medications in the United States.

ANSWER: MSN admits that it is a corporation organized under the laws of India and that it entered into a certain Collaboration and Supply Agreement, a copy of which purports to be attached to the Complaint as **Exhibit 1** (the "Agreement") with Nexgen. MSN denies the remaining allegations of paragraph 1.

2. Pursuant to the agreement, Nexgen paid approximately \$800,000 to fund attempts to obtain FDA approval of the MSN-manufactured medications and, in exchange, was to receive exclusive distribution rights for the medications and a fifty percent share of the net profits.

ANSWER: MSN admits that the Agreement speaks for itself. MSN denies any remaining allegations in paragraph 2.

3. MSN materially breached the agreement by refusing to permit Nexgen to distribute the medications after approval, instead forming a US subsidiary and giving it exclusive distribution rights.

ANSWER: Paragraph 3 contains legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations in paragraph 3.

PARTIES AND JURISDICTION

4. Plaintiff Nexgen Lifesciences, LLC is a Wyoming limited liability corporation, with its principal place of business located at 8913 Regents Park Drive, Suite #550, Tampa, Florida 33647. The members of Nexgen Lifesciences, LLC are trusts, the trustees of which are citizens of Florida and Virginia.

ANSWER: MSN is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies them.

5. Defendant MSN Laboratories Private Limited is a foreign company organized under the laws of India with a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanath Nagar, Hyderabad 50018, A.P.

ANSWER: MSN admits the allegations of Paragraph 5.

6. This Court has jurisdiction under 28 U.S.C. § 1332(a) because the controversy exceeds the sum or value of \$75,000.00, exclusive of interest and costs, and all parties are diverse as Plaintiff is a citizen of a state(s) in the United States and Defendant is a citizen and/or subject of a foreign state.

ANSWER: Paragraph 6 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, MSN does not contest subject matter jurisdiction for purposes of this civil action only. MSN denies any remaining allegations in paragraph 6.

7. This Court has jurisdiction over MSN pursuant to a binding forum selection clause within an agreement that was negotiated and executed by MSN and Nexgen.

ANSWER: Paragraph 7 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the Agreement speaks for itself

and MSN does not contest subject matter jurisdiction for purposes of this civil action only. MSN denies any remaining allegations in paragraph 7.

8. Venue is appropriate in this Court pursuant to a binding forum selection clause within an agreement that was negotiated and executed by MSN and Nexgen.

ANSWER: Paragraph 8 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, MSN does not contest venue in this Court for purposes of this civil action only. MSN denies any remaining allegations in paragraph 8.

9. Even in the absence of the forum selection clause, venue would be appropriate in this jurisdiction because MSN, through its subsidiaries, operates in New Jersey.

ANSWER: Paragraph 9 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, MSN does not contest venue in this Court for purposes of this civil action only. MSN denies any remaining allegations in paragraph 9.

10. MSN operates dosage manufacturing facilities in New Jersey through its subsidiary MSN Pharmaceuticals Inc, which distributes the drugs in question in the United States. MSN Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at Piscataway, New Jersey.

ANSWER: MSN admits that MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at Piscataway, New Jersey. MSN denies the remaining allegations of Paragraph 10.

11. MSN's sales and marketing subsidiary, Novadoz Pharmaceuticals, LLC operates from offices in Piscataway, New Jersey. Upon information and belief, Novadoz Pharmaceuticals, LLC is an LLC formed in New Jersey whose members are citizens of the State of New Jersey.

ANSWER: MSN admits that Novadoz Pharmaceuticals, LLC exists under the laws of the State of New Jersey and has its principal place of business in New Jersey. MSN denies the remaining allegations of paragraph 11.

GENERAL ALLEGATIONS

12. Nexgen is a company that was formed to provide sales and marketing infrastructure in the United States and to collaborate with pharmaceutical companies to develop, register, and commercialize pharmaceutical products throughout the United States.

ANSWER: MSN is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 12, and therefore denies them.

13. MSN is a pharmaceutical company that develops finishing dosage formulations for various pharmaceutical products globally, including for distribution in the United States.

ANSWER: MSN admits that it is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products in the United States. MSN will not contest personal jurisdiction in this Court for purposes of this civil action only and only for claims that are properly before this Court. MSN denies any other allegations contained in Paragraph 13.

14. In 2015, Nexgen and MSN began negotiating an opportunity for MSN to develop and deliver, and Nexgen to exclusively distribute the pharmaceutical compounds MOXIFLOXACIN HYDROCHLORIDE (Oral Tablets 400 mg), CAPECITABINE (Oral Tablets 150mg and 500mg), and ROSUVASTATIN CALCIUM (Oral Tablets 40mg, 20, mg, 10mg, and 5mg) (the “Compounds”).

ANSWER: MSN admits that the Agreement speaks for itself. MSN denies the remaining allegations of Paragraph 14.

15. MSN and Nexgen negotiated the terms of their business relationship and memorialized the agreement in a Collaboration and Supply Agreement and Annexure 1 to Generic Finished Pharmaceutical Formulation Term Sheet Between Nexgen Life Sciences & MSN Laboratories Private Limited (the “Agreement”), attached as **Exhibit 1**.

ANSWER: MSN admits that the Agreement speaks for itself. MSN denies the remaining allegations of Paragraph 15.

16. Under the terms of the Agreement, MSN agreed to supply the Compounds to Nexgen, give Nexgen the exclusive right to distribute the Compounds in the United States and Puerto Rico, and share 50% of the net profits from the sale of the Compounds for seven years.

ANSWER: MSN admits that the Agreement speaks for itself. MSN denies the remaining allegations of Paragraph 16.

17. MSN materially breached the Agreement by failing to supply the Compounds to Nexgen, refusing to allow Nexgen to exclusively distribute and sell the Compounds in the United States and Puerto Rico, distributing the Compounds without Nexgen’s involvement despite its exclusive contract with Nexgen, and denying Nexgen its 50% share of the net profits stemming from the sale of the Compounds.

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, the Agreement speaks for itself. MSN denies the remaining allegations of Paragraph 17.

18. On multiple occasions, Nexgen attempted to resolve these issues with MSN, consistent with the terms of the Agreement, but they were unable to reach a resolution. All conditions precedent to the maintenance of this action have occurred, have been performed, or have been waived.

ANSWER: Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, denied.

CAUSES OF ACTION

COUNT I
Breach of Contract

19. Nexgen readopts and realleges paragraphs 1 through 18 of this Complaint as if fully set forth herein.

ANSWER: MSN incorporates the answers to paragraphs 1-18 as if fully set forth herein.

20. This is an action for breach of contract against MSN.

ANSWER: Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, denied.

21. The Agreement between Nexgen and MSN is an enforceable contract.

ANSWER: Paragraph 21 contains legal conclusions to which no response is required.

22. MSN has materially breached the terms of the Agreement by, inter alia, failing to supply the Compounds to Nexgen, refusing to allow Nexgen to exclusively distribute and sell the Compounds in the United States and Puerto Rico, distributing the Compounds without Nexgen's involvement despite its exclusive contract with Nexgen, and denying Nexgen its 50% share of the net profits stemming from the sale of the Compounds.

ANSWER: Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, denied.

23. Even if MSN argues that it terminated the Agreement for cause, it has still materially breached the terms of the Agreement by refusing to honor its obligations under Section 5.3.2.1 of the Agreement which states that in the event of termination for cause by MSN, all rights

of NLS “shall remain in effect on an irrevocable, perpetual, non-exclusive, fully paid-up and royalty-free basis.”

ANSWER: Paragraph 23 contains legal conclusions to which no response is required. To the extent a response is required, the Agreement speaks for itself. MSN denies the remaining allegations of Paragraph 23.

24. As a direct result of MSN’s breach, Nexgen has been damaged in an amount to be determined at trial.

ANSWER: Paragraph 24 contains legal conclusions to which no response is required. To the extent a response is required, denied.

COUNT II **Declaratory Judgment**

25. Nexgen readopts and realleges paragraphs 1 through 24 of this Complaint as if fully set forth herein.

ANSWER: MSN incorporates the answers to paragraphs 1-24 as if fully set forth herein.

26. An actual controversy has arisen between Nexgen and MSN in that, as described above, MSN has refused to grant Nexgen exclusive rights to distribute the Compounds in the United States and Puerto Rico and to pay Nexgen 50% of net profits from the sale of the Compounds.

ANSWER: Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is required, denied.

27. Nexgen seeks a declaration under 28 USCA §2201 that pursuant to Section 5.3.2.1 of the Agreement, Nexgen has exclusive rights to distribute the Compounds in the United States and Puerto Rico.

ANSWER: Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, denied.

28. Nexgen further seeks a declaration that pursuant to Section 3.12 of the Agreement it is entitled to 50% of the net profits from sales of the Compounds for seven years.

ANSWER: Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, denied.

29. A judicial determination is necessary and appropriate at this time and under these circumstances for the Parties to ascertain their rights and obligations to one another.

ANSWER: Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is required, denied.

COUNT III
Unjust Enrichment / Restitution
(Plead in the alternative)

30. Nexgen readopts and realleges paragraphs 1 through 24 of this Complaint as if fully set forth herein.

ANSWER: MSN incorporates the answers to paragraphs 1-24 as if fully set forth herein.

31. Nexgen has conferred a benefit on MSN in the amount of over \$800,000.00.

ANSWER: Paragraph 31 contains legal conclusions to which no response is required. To the extent a response is required, denied.

32. MSN has knowledge of the benefit.

ANSWER: Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, denied.

33. MSN has accepted or retained the benefit conferred to it by Nexgen by knowingly keeping the funds given to MSN by Nexgen and refusing to repay Nexgen any of the amount.

ANSWER: Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required, denied.

34. The circumstances are such that it would be inequitable for MSN to retain the benefit of over \$800,000.00 without giving fair value for it.

ANSWER: Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, denied.

GENERAL DENIAL AND RESPONSE TO THE PRAYER FOR RELIEF

Any allegations in the Complaint not expressly admitted by MSN are denied. MSN denies that Plaintiffs are entitled to any judgment or relief requested in Paragraphs a through c of their “Prayer for Relief.”

DEMAND FOR JURY TRIAL

ANSWER: contains no factual allegations that require a response. MSN reserves all rights to request a jury trial.

AFFIRMATIVE DEFENSES

Any allegation of any defense below is not an admission that MSN bears the burden on proof or persuasion on any claim or issue.

First Affirmative Defense – Failure to State a Claim

Nexgen fails to state a claim upon which relief may be granted and/or fails to state any facts to support a claim upon which relief may be granted.

Second Affirmative Defense – Laches

Nexgen has unreasonably delayed in asserting the allegations and claims for relief pled in the Complaint. MSN relied upon or was induced to act on this delay, which caused prejudice and detriment to MSN.

Third Affirmative Defense – Equitable Estoppel

Nexgen knowingly misrepresented or concealed material facts of which MSN was not aware. MSN relied on Nexgen's representations in good faith, which caused prejudice and detriment to MSN.

Fourth Affirmative Defense – Waiver and/or Interference

Nexgen waived the right to insist on performance by MSN to develop ROSUVASTATIN CALCIUM and CAPECITABINE, because, among other things, Nexgen failed to pay the required cost sharing and/or milestone payments for their development. In failing to make the required payments, Nexgen also prevented and/or hindered MSN's continuing performance.

Fifth Affirmative Defense – Termination

Nexgen agreed to terminate the development and commercialization of MOXIFLOXACIN HYDROCHLORIDE for commercial non-viability.

Sixth Affirmative Defense – Failure to Mitigate Damages

Nexgen is not entitled to the damages it seeks, including interest and/or attorneys' fees, because it allowed them to add up unnecessarily by, among other things, refusing to obtain a reasonable settlement offered by MSN and failing to take prompt action on its claims. Furthermore, Nexgen's breach of the agreement between the parties caused damages to MSN in excess of those claimed by Nexgen such that if a breach by MSN is found, MSN is entitled to a set-off and recovery of damages from Nexgen.

Seventh Affirmative Defense – No Breach of Contract

MSN complied with the terms of the Agreement and/or was prevented or excused from such performance.

Eighth Affirmative Defense – Unjust Enrichment

Nexgen is seeking to receive higher damages that would be warranted under the Agreement.

Ninth Affirmative Defense – Failure of Condition Precedent

Nexgen did not comply with the terms of the Agreement, which it was required to do prior to bringing its claims. MSN was not required to act under the Agreement until Nexgen properly and timely made the required cost sharing and/or milestone payments, which it failed to do.

Tenth Affirmative Defense – Prior Breaches

Nexgen's claims are barred by its prior breaches, as described in the accompanying counterclaims.

Eleventh Affirmative Defense – Failure to Perform and/or Lack of Consideration

Nexgen's claims are barred because, *inter alia*, it failed to perform all conditions precedent to MSN's performance under the agreement between the parties. Nexgen's claims fail in whole or in part due to lack of consideration for certain terms alleged by Nexgen, including but not limited to alleged promises by Nexgen to make certain payments.

Twelfth Affirmative Defense – Statute of Limitations

Nexgen's claims are barred, in whole or in part, by the statute of limitations.

Thirteenth Affirmative Defense – No Entitlement to Attorneys' Fees

Nexgen is not entitled to attorneys' fees against MSN because, *inter alia*, Nexgen has not sufficiently alleged, and cannot prove, that this case is exceptional or warrants the imposition of fees for any reason.

WHEREFORE, MSN respectfully requests that the Complaint be dismissed with prejudice, that MSN be awarded its attorney's fees and costs, and that this Honorable Court enter such other Order as it deems just and proper.

COUNTERCLAIMS

In further response to the Complaint, MSN Laboratories Private Limited ("MSN") alleges the following Counterclaims, without prejudice to any denial in its Answer, and without admission to any allegation in the Complaint (unless otherwise explicitly admitted above), without prejudice of the rights of MSN to plead additional Counterclaims as the facts of the matter warrant, and without assuming any burden when such burden would otherwise be that of Nexgen Lifesciences, LLC ("Nexgen").

Parties

1. Counterclaimant MSN Laboratories Private Limited is a corporation organized under the laws of India with a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanath Nagar, Hyderabad 50018, A.P.

2. On information and belief, Counterclaim Defendant Nexgen Lifesciences, LLC is a Wyoming limited liability corporation, with its principal place of business located at 8913 Regents Park Drive, Suite #550, Tampa, Florida 33647.

Jurisdiction and Venue

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1337. MSN's counterclaims relate to the claims made by Counterclaim Defendant that are based upon purported breach of contract. The Court also has jurisdiction over MSN's request for declaratory relief pursuant to 28 U.S.C. §§2201-02.

4. The Court has personal jurisdiction over Nexgen by virtue of the Complaint filed by Nexgen in this Court and by virtue of Nexgen's significant and persistent contacts with this forum both generally and specifically as it relates to the performance of the transactions and occurrences identified in the Complaint.

Facts

5. Nexgen and MSN entered into a certain Collaboration and Supply Agreement and Annexure 1 to Generic Finished Pharmaceutical Formulation Term Sheet Between Nexgen Life Sciences & MSN Laboratories Private Limited (the "Agreement"), attached hereto as **Exhibit 1**.

6. Pursuant to the terms of the Agreement, the parties initially agreed to pursue three products, i.e., ROSUVASTATIN CALCIUM, CAPECITABINE, and MOXIFLOXACIN HYDROCHLORIDE.

7. Also pursuant to the terms of the Agreement, Nexgen was to pay certain milestone payments and cost sharing payments upon the occurrence of certain dates and events.

8. On information and belief, the Parties agreed to terminate the commercialization of MOXIFLOXACIN HYDROCHLORIDE for commercial non-viability.

9. On information and belief, Nexgen did not pay the required cost sharing and milestone payments related to CAPECITABINE as required under the Agreement.

10. With respect to ROSUVASTATIN CALCIUM, on information and belief, Nexgen paid a total of \$451,855 toward its development (the "Paid Cost") and according to the Agreement, Nexgen still owes \$54,242 in milestones.

COUNT I BREACH OF CONTRACT

11. MSN hereby incorporates the allegations of the preceding paragraphs of these counterclaims as if fully set forth herein.

12. A valid and enforceable contract existed between the parties, i.e., the Agreement.

13. The contract imposed several duties upon Nexgen, including the payment of certain cost sharing and milestones at certain times and events.

14. Nexgen materially breached the contract by failing to make those payments, as contractually required.

15. Even if Nexgen argues that it terminated the Agreement for cause, it has still materially breached the terms of the Agreement by refusing to honor its obligations under Section 5.2.1 of the Agreement.

16. As a direct and proximate result of Nexgen's breaches, MSN incurred monetary damages in an amount to be proven at trial.

**COUNT II
DECLARATORY JUDGMENT**

17. MSN hereby incorporates the allegations of the preceding paragraphs of these counterclaims as if fully set forth herein.

18. An actual controversy has arisen between MSN and Nexgen in that, as described above, Nexgen has failed to make the required cost sharing and milestone payments pursuant to the Agreement.

19. MSN seeks a declaration under 28 USCA §2201 that pursuant to Section 5.3.1 of the Agreement, Nexgen is required to make payment accrued prior to termination.

20. A judicial determination is necessary and appropriate at this time and under these circumstances for the Parties to ascertain their rights and obligations to one another.

PRAYER FOR RELIEF

WHEREFORE, MSN respectfully requests that this Court enter judgment in its favor and against Nexgen in an amount proven at trial, plus interest, attorney's fees, costs of litigation, expert witness fees, and such other relief as this Court deems just and proper.

Dated: August 15, 2022

By:

/s/ Eric I. Abraham

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